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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,498	02/12/2004	Donald P. Ewing	1456-2U	5239

31292 7590 01/22/2009

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EXAMINER	
CEGIELNIK, URSZULA M	

ART UNIT	PAPER NUMBER
3711	

MAIL DATE	DELIVERY MODE
01/22/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/777,498	EWING ET AL.	
	Examiner	Art Unit	
	Urszula M. Cegielnik	3711	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,6,8,13-16,18-21 and 48-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,6,8,13-16,18-21 and 48-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4, 6, 8, 19-21, and 48-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilbert (US Patent No. 6,961,622) in view of North et al. (US Patent No. 7,142,923).

Gilbert discloses a housing (col. 6, line 12) conformable to a portion of a body, said housing being formed by one or more layers of water resistant material (the layers are substantially water resistant being made of polyethylene (which is thermoplastic) foam and protecting circuitry to a degree); a control circuit connected directly to two or more electrodes wherein said control circuit and said electrodes are substantially contained within the housing (col. 5, lines 60-67 through col. 6, lines 1-4); and a layer of electrical insulation surrounding at least a portion of the control circuit; a body; and wherein said apparatus is attachable to said body with adhesive comprising one or more electrogel pads; voltage intensity control; a battery (46); hydrogel; display indicating status and intensity.

Gilbert does not explicitly disclose a microprocessor having programmable intensities according to duty cycles; the duty cycles having the claimed ranges; the polymeric material of the housing being polyvinyl chloride.

North et al. teaches a neurostimulator that has a microprocessor that may be programmed to include different intensities with duty cycles.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a microprocessor as taught by North et al., since such a modification would permit specific intensity values with respect to a duty cycle to be given.

With regard to the number of intensities having a duty cycle, North et al. teaches a plurality of programs that each include a duty cycle. Because of the programmable capability of the microprocessor, it would logically follow that a third program with a corresponding duty cycle may be provided.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the number of intensities with a corresponding duty cycle being three as taught by North et al., since such modification would enhance the functionality of the device.

With regard to the claimed duty cycles each having a claimed range (value), North et al. teach programming the microprocessor to provide specific values of duty cycles in order to carry out programmed treatment.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide duty cycles with a range of values as taught by North et al., since such a modification would permit programmed treatment to be carried out.

With regard to the claimed duty cycles each having a claimed range (value), it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide first, second, third duty cycles with ranges 9 and 14%, 26 and 31%, and 47 and 53% (values of 45 milliseconds and 93 milliseconds), respectively, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller, 105 USPQ 233.*

With regard to the polymer housing being polyvinyl chloride, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the housing made of polyvinyl chloride, since the examiner takes Official Notice of the equivalence of polyvinyl chloride and polyethylene for their use in the foam art and the selection of any of these shown equivalents to provide a foam housing would be within the level of ordinary skill in the art.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 1 above, and further in view of Silverstone (US Patent No. 6,351,674).

The modified invention of Gilbert lacks an adjustable voltage intensity ranging from 90 to 180 volts.

Silverstone teaches an electrical stimulation device with voltages in the range between 90 and 180 volts (col. 3, lines 19-20).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the abovementioned claimed features as taught by Silverstone, since Silverstone states at col. 3, lines 19-20, that such voltages are known of typical stimulators.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 1 above, and further in view of Liss et al. (US Patent No. 5,851,223).

The modified invention of Gilbert lacks the apparatus outputting a square waveform at a constant current.

Liss et al. teach an apparatus outputting a square waveform at a constant current (see Figure 1C, for example).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the abovementioned claimed feature as taught by Liss et al., since such a modification would permit the timing of the control circuitry.

Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 1 above, and further in view of Thomas (US Patent No. 5,107,835).

The modified invention of Gilbert lacks the apparatus using a frequency of approximately 0.1 to 4000 Hertz.

Thomas teaches an apparatus using a frequency of approximately 0.1 to 4000 Hertz (col. 2, lines 19-25).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the abovementioned claimed feature as taught by Thomas, since Thomas states at col. 2, lines 19-20 that such a modification would decrease inflammation in an afflicted region in a patient.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 1 above, and further in view of DiLorenzo (US Patent Application Publication No. 2003/0018367).

The modified invention of Gilbert lacks the apparatus having a pulse width of approximately 45 milliseconds and a range from .01 microsecond to 50 milliseconds.

DiLorenzo teaches an apparatus having a pulse width in the range of 1 microsecond and 1000 milliseconds (paragraph 0100, lines 8-10).

With regards to providing a pulse width from the range of .01 microsecond, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a pulse width from the range of .01 microsecond, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill n the art. *In re Aller, 105 USPQ 333.*

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 1 above, and further in view of Zilber (US Patent No. 3,822,708),

The modified invention of Gilbert lacks the apparatus outputting approximately thirty pulses over a four-second duration.

Zilber teaches an apparatus outputting 5 to 200 pulses per second (col. 4, line 9).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the abovementioned claimed feature as taught by Zilber, since such a modification would permit a certain value of current to be passed.

With regards to providing the time period being four seconds, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a time period being four seconds, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill n the art. *In re Aller, 105 USPQ 333.*

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Urszula M. Cegielnik whose telephone number is 571-272-4420. The examiner can normally be reached on Monday through Friday, from 5:45AM-2:15PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eugene L. Kim can be reached on 571-272-4463. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/umc/
/Gene Kim/
Supervisory Patent Examiner, Art Unit 3711